UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC.. Defendant.	Civil Action No. 06-222 (JJF) **PUBLIC VERSION**

IMPAX LABORATORIES, INC.'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT, LACK OF WRITTEN DESCRIPTION, LACK OF ENABLEMENT, MISJOINDER OF INVENTORS, AND INDEFINITENESS

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I. INTRODUCTION

Wyeth described its invention as a specific extended release formulation of venlafaxine comprising certain ingredients. Wyeth's claims, properly construed, are limited to that specific formulation. As a result, Impax's formulation, which contains different ingredients, cannot literally infringe. Nor can Wyeth avoid a judgment of non-infringement by resorting to the doctrine of equivalents. That doctrine is intended to protect a patentee from an unduly restrictive claim scope when the patentee could not have anticipated the particular equivalent and thus could not have claimed it expressly. Here, however, Wyeth disclosed but failed to claim different ingredients, and thus cannot recapture that claim scope. Moreover, during the prosecution of the patents in suit, Wyeth expressly disclaimed and thus surrendered the coverage it now seeks. For these reasons, Impax does not infringe the patents in suit.

In the alternative, if the Court adopts a broader claim scope, then the claims are invalid for lack of written description. The patent specification makes clear that the inventors had possession of only a single invention—a formulation containing MCC and, optionally, HPMC. And because the patents explicitly teach against the use of the binder Impax uses, the specification also cannot have enabled claims broad enough to cover Impax's product.

II. STATEMENT OF UNDISPUTED FACTS[1]

A. Wyeth's development of Effexor XR

1. Wyeth obtained a patent on venlafaxine as a treatment for depression.

In 1983, Wyeth filed for a patent on the chemical compound now known as venlafaxine. U.S. Patent No. 4,535,186 (the "'186 patent") issued on August 13, 1985 and will expire on December 13, 2007.[2] The '186 patent's specification explains that venlafaxine is useful to treat

[1] This Statement of Undisputed Facts is identical to the Statement of Undisputed Facts contained in Impax's contemporaneously-filed Motion For Summary Judgment of Anticipation, Obviousness, Inventorship, And Indefiniteness.

[2] Declaration of Mary Matterer in Support of Impax Laboratories, Inc.'s Motions for Summary Judgment, Ex. 1 ('186 patent).

depression.[3] Wyeth first marketed Effexor, an immediate-release formulation of venlafaxine, in 1994. Since then, Wyeth has made billions of dollars from sales of venlafaxine.[4]

2. Wyeth developed Effexor XR in order to increase patient convenience.

Wyeth's initial venlafaxine product, Effexor, was an immediate-release formulation typically taken by patients two or three times a day.[5] REDACTED

Wyeth began developing a once-a-day formulation of venlafaxine.[6] Wyeth's reason for doing so was straightforward: REDACTED

[7] Wyeth's 30(b)(6) witness conceded that REDACTED Internal Wyeth documents confirm that its extended-release venlafaxine product was nothing more than REDACTED

3. REDACTED

Extended release formulation techniques have been known in the art and taught in pharmacy schools since the 1950s. Since then, a limited number of extended-release techniques have been used in countless products with different active ingredients.[10] Wyeth itself has

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[3] Ex. 1 ('186 patent (cover page)).

[4] *See* Towle Markman Decl., D.I. 194, Ex. A-E (Wyeth annual reports showing revenues from Effexor).

[5] Ex. 2 (excerpt from Effexor XR NDA) at WYETH 004-000299.

[6] REDACTED

[7] REDACTED

[8] Ex. 5 (Enever Depo.) at 39:1-7.

[9] Ex. 6 REDACTED WYETH 004-000326-361 at 330.

[10] *See, e.g.*, *infra* sections II.A.4-5.

developed and marketed several different extended-release products.[11]

Wyeth began its development of an extended release venlafaxine formulation by

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4. Wyeth failed to make extended-release venlafaxine as a hydrogel tablet.

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[11] *See id.*

[12] REDACTED

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[13] REDACTED

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[16] REDACTED

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As the patents-in-suit disclose, the hydrogel tablets Sherman made dissolved too rapidly: "Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies."[20] Wyeth eventually concluded that developing a venlafaxine tablet using hydrogel technology was "impossible," and pursued that avenue no further.[21]

5. Wyeth succeeded in developing extended-release venlafaxine using a preexisting process for making coated spheroids.

Wyeth next decided to put venlafaxine in the dosage form it had successfully used with a different drug, also similar to venlafaxine, called REDACTED[22] The REDACTED dosage form consisted of coated spheroids created by the process of "extrusion and spheronization."[23] This process creates spheroids having a core composed of a pharmaceutically active ingredient mixed with a matrix former/binder such as microcrystalline cellulose ("MCC").[24] First, the active

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[17] Ex. 3 REDACTED

[18] Ex. 10 REDACTED

[19] *Id.* at REDACTED

[20] Ex. 11 (U.S. Patent No. 6,274,171 B1 ("'171 Patent")) at 4:60-64.

[21] *Id.* at 10:53-55.

[22] REDACTED

[23] REDACTED

[24] A matrix is a tightly-held, uniform mixture of material within which the drug is housed.

ingredient is mixed with MCC and water to activate the binder and create an elastic mass that has a putty-like texture.[25] Second, this wet, putty-like mass is processed through an "extruder," a machine which presses the material through small holes in a metal plate, creating strands of "extrudate" shaped like short pieces of spaghetti.[26] Third, the extrudate is placed in a "spheronizer," a machine consisting of a bowl with a grooved, rapidly rotating bottom.[27] In the spheronizer, frictional forces break the extrudate into uniform pieces and round them off into spheroids. A coating that slows the dissolution of the spheroids is then applied.[28]

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Throughout this brief, the unwieldy term "microcrystalline cellulose" will be silently abbreviated "MCC."

[25] *See, e.g.*, Ex. 11 ('171 patent) at 1:37-58.

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] REDACTED

[30] REDACTED

[31] REDACTED

[32] REDACTED

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a. Wyeth used the same extension and spheronization technique it had used successfully

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Once the manufacture of spheroids moved out of the laboratory and onto larger-scale equipment, Wyeth learned that HPMC was not an essential ingredient: "Subsequent experiments carried out on Hutt and Nica extruders surprisingly demonstrated that acceptable, and even improved, spheroids could be made without the use of an hydroxypropylmethylcellulose."[45]

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b. Wyeth based the coating on its propranolol product.

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Clark hit on the formula set forth in the patents: "from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP."[48] REDACTED

41 REDACTED

42 REDACTED (Impax will refer to "hydroxypropylmethylcellulose" as "HPMC.").

43 REDACTED

44 REDACTED

45 Ex. 11 ('171 Patent) at 6:6-11.

46 REDACTED

47 REDACTED

48 Ex. 11 ('171 Patent) at 3:37-40; REDACTED

This coating is very similar to that disclosed in the '475 patent for the extended release formulation of propranolol. Ex. 16 (U.S. Patent No.

REDACTED

REDACTED

B. The Alza extended-release venlafaxine formulation.

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4,138,475 ("'475 Patent")) at 1:58-63 ("The film coating may, for example, comprise 80 to 100% by weight of ethylcellulose and 20 to 0 % by weight of hydroxypropyl methylcellulose.").

49 REDACTED

50 REDACTED

51 REDACTED

52 REDACTED

53 REDACTED

54 REDACTED

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Subsequently, on December 8, 1994, Alza published the details of Alza's extended-release venlafaxine formulation as an international patent application pursuant to the Patent Cooperation Treaty ("PCT"), No. WO94/27589.[56] The PCT application expressly disclosed an extended-release venlafaxine formulation that was "useful for antidepressant therapy" and "a method useful for antidepressant therapy by administering the controlled-release dosage form comprising the compound of the invention."[57] The PCT application further disclosed specific examples of formulations of the invention,

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Alza was ultimately granted United States Patent No. 6,440,457, covering its extended-release venlafaxine formulation. The sole claim recites:

> A method for administering a drug to the gastrointestinal tract of a human, wherein the method comprises: (a) admitting orally into the human a dosage form comprising [venlafaxine] which drug possess antidepressant therapy and the dosage form comprises a member selected from the group consisting of a sustained-release dosage form and a controlled-release dosage form; and, (b) administering the drug from the dosage form over an extended period of time in a therapeutically responsive dose to produce the antidepressant therapy.[61]

Alza asserted this patent against Wyeth, claiming that using Effexor XR infringes.[62] In

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[56] Ex. 22 (Alza PCT Application).

[57] *Id.* at 1.

[58] *Id.* at 22-24 (Examples 1 and 2).

[59] REDACTED

[60] *Id.* at 175:1-176:8.

[61] Ex. 24 (U.S. Patent No. 6,440,457) at 14:28-48.

[62] Ex. 25 (Complaint in *Alza v. Wyeth*, No. 9:06-cv-00156-RHC (E. D. Tex. filed July 26, 2006)).

response, on July 28, 2006, Wyeth requested that the PTO reexamine the '457 patent.[63] In its reexamination request, Wyeth argued that the '457 patent should never have issued, since it was anticipated by an earlier patent that disclosed an extended-release dosage form just like the one Alza used, except that it did not disclose the use of venlafaxine as the active pharmaceutical ingredient.[64] Alza had argued in the original examination proceeding that this earlier patent did not anticipate, since the "very high solubility" of venlafaxine rendered it unlike those drugs used with the dosage form in the past.[65] The examiner disagreed, holding that because the prior art dosage form could be used to deliver sodium nitrate, a drug with high solubility, "it will deliver venlafaxine." Despite this disagreement, the '457 patent ultimately issued after an appeal.[66]

In its reexamination request, Wyeth argues that the examiner's initial rejection—on the ground that an extended-release dosage form which can deliver one water soluble drug can be expected to deliver another—was the right result. While the reexamination is still ongoing, the PTO's initial office action ruled in favor of Wyeth, holding that a skilled artisan would be motivated to combine references to create an extended-release venlafaxine formulation for reasons well-known in the art:

> The artisan is motivated to provide sustained and controlled release dosage forms for any of the art recognized advantages that these formulations provide. In particular, Gupta teaches the advantages of reduced dosing frequency, better patient convenience and compliance, reduced GI side effects and other toxic effects, less fluctuating plasma drug levels, more uniform drug effect, and lesser total dose.[67]

Alza submitted a response to this Office Action on March 19, 2007, and awaits final action by the PTO.[68]

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[63] Ex. 26 (7/28/06 Reexamination Request) at WYETH331-000015.

[64] *Id.* at WYETH331-000022.

[65] *Id.* at WYETH331-000023.

[66] *Id.*

[67] Ex. 27 (February 16, 2007 Office Action in Reexamination Control No. 90/008,142) at 10.

[68] Ex. 28 (docket sheet in Reexamination Control No. 90/008,142).

C. Wyeth's clinical trials confirmed the therapeutic effect of the extended release product.

Wyeth conducted clinical trials in order to gain FDA approval for Effexor XR. The three key studies are:

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D. Wyeth's prosecution of the patents-in-suit.

Wyeth has asserted three patents in this case: U.S. Patent Nos. 6,274,171,[74] 6,403,120,[75] and 6,419,958.[76] The patents share a common specification and common inventors: each lists as

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[69] Ex. 29 (208 study) at WYETH004-013235.

[70] Ex. 30 (209 study) at WYETH004-014380.

[71] Ex. 31 (367 study) at WYETH004-015402.

[72] Ex. 32 (Deposition of Ronald Thisted) at 57:13-58:20.

[73] Ex. 29 (208 study) at WYETH004-013318

[74] Ex. 11 ('171 Patent).

[75] Ex. 33 (U.S. Patent 6,403,120 ("'120 patent")).

[76] Ex. 34 (U.S. Patent 6,419.958 ("'958 Patent")).

its inventors Wyeth employees Deborah Sherman, John Clark, John Lamer, and Steven White.[77]

The patent begins by asserting that extended release formulations are conventionally prepared using hydrogel tablet technology.[78] The patent recounts Sherman's "failed experiments" to make a hydrogel extended-release formulation,[79] and tells of Sherman's early failed attempts to make spheroids without using HPMC:

> Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose and HPMC, different ratios of venlafaxine hydrochloride and filler, different binders such as PVP, methylcellulose, water, and polyethylene glycol of different molecular weight ranges in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of HPMC 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.[80]

Wyeth contended in the specification that it was "completely unexpected" that an extended release formulation of venlafaxine could be made given the drug's high water-solubility.[81] The specification then explains how the inventors solved this purported problem: "[t]he formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, MCC and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC."[82] The patent explains that other grades of MCC and HPMC maybe substituted "without changing the inventive concept."[83]

The specification asserts that administering the formulation of the invention offers patients two benefits. First, it asserts that "use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis

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[77] Ex. 11 ('171 Patent); Ex. 33 ('120 Patent); Ex. 34 ('958 Patent).

[78] Ex. 11 ('171 Patent) at 1:13-15. Citations to the common specification will be made to the '171 patent throughout.

[79] *Id.* at 6:6.

[80] *Id.* at 5:1-13.

[81] *Id.* at 4:57-60.

[82] *Id.* at 2:63-3:2.

[83] *Id.* at 4:44-48.

that attend the administration of multiple daily dosing."[84] Second, it contends that "[t]hrough administration of the venlafaxine formulation of this invention, there is provided . . . a method for eliminating the sharp peaks and troughs (hills and valleys) in blood plasma drug levels induced by multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets."[85]

In the first (non-provisional) application in the chain that led to the issuance of the patents-in-suit, Wyeth initially proposed formulation claims that were explicitly limited to formulations of venlafaxine, MCC, and HPMC.[86] Wyeth also proposed method claims similar to those at issue here, which did not explicitly recite the ingredients of the formulation to be administered using the claimed method.[87]

The examiner found the method claims unpatentable over a prior art patent which explicitly disclosed administering venlafaxine in a "sustained oral administration form or time-release form, which may be used to spread the doseage [sic] over time, such as for once-a-day applications."[88] The examiner insisted that Wyeth make explicit that its method claims were limited to the formulations described in the specification.[89] Wyeth **agreed** that the method claims would be amended to make them depend from the narrow formulation claims.[90] The examiner made an amendment to the claims consistent with that agreement, and Wyeth had the opportunity to make a further amendment if it objected to the examiner's action. Wyeth

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[84] *Id.* at 2:46-49.

[85] *Id.* at 2:23-28.

[86] Ex. 35 (excerpt from file history of U.S. Patent App. No. 08/821,137) at WYETH 002-000804-005. The optional nature of HPMC first appeared in U.S. Patent App. No. 08/964,328. Ex. 36 (excerpt from file history of U.S. Patent App. No. 08/964,328) at WYETH 002-000580-083.

[87] Ex. 35 (excerpt from file history of U.S. Patent App. No. 08/821,137) at WYETH 002-000804-005.

[88] *Id.* at WYETH002-000850 ("Agreed to amend claims 9 and 10 to depend from claim 1 to avoid rejection over Upton which discloses extended release venlafaxine at col 5, lines 25-27."); *see* Ex. 37 (U.S. Patent No. 5,506,270 ("'270 Patent")) at 5:25-27 (disclosing extended release venlafaxine, as cited by the examiner).

[89] Ex. 35 (excerpt from file history of U.S. Patent App. No. 08/821,137) at WYETH002-000850.

[90] *Id.*

acquiesced in the examiner's action, and the examiner then issued a Notice of Allowance.[91]

Instead of filing an amendment as the examiner had instructed, and without any explanation, Wyeth abandoned that application after the Notice of Allowance had issued and filed a new application which was assigned to a different examiner.[92] Wyeth then re-proposed method claims virtually identical to the original (unamended) claims from the earlier application.[93] Wyeth did not tell the new examiner about the prior application, nor that a different examiner had rejected virtually identical claims and that Wyeth had agreed to amend these claims in order to overcome the prior art. After another abandonment and re-filing, the new examiner allowed the method claims to issue.[94] Wyeth has never offered any explanation for this conduct.

E. Impax's ANDA

On December 15, 2005, Impax filed ANDA No. 78-057 with the FDA.

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F. The Prior Art

United States Patent No. 4,138,475 issued on February 6, 1979. It teaches an extended-release formulation of the drug propranolol. The formulation described in the '475 patent is the

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[91] *Id.* at WYETH 002-000907.

[92] *Id.* at WYETH 002-000911 (abandoning the '137 application, which was assigned to Examiner Hulina); Ex. 36 (excerpt from file history of U.S. Patent App. No. 08/964,328) at WYETH 002-000715-720 (indicating assignment of the '328 Application to Examiner Spear).

[93] Ex. 36 (excerpt from file history of U.S. Patent App. No. 08/964,328) at WYETH 002-000582.

[94] Exh. 11 ('171 Patent (cover page)) (listing Examiner Spear as the Primary Examiner); *Id.* at 12:63-13:12 (setting forth method claims identical to those rejected by Examiner Hulina in the '137 Application).

[95] REDACTED

[96] *Id.*

same as that described in the patents-in-suit, except for the substitution of a different active pharmaceutical ingredient: it is created by extrusion and spheronization,[97] uses MCC as a matrix, blended with the active pharmaceutical ingredient,[98] comprises spheroids coated with an extended-release mixture of ethylcellulose and HPMC,[99] and includes placing those spheroids in a capsule.[100]

United States Patent No. 4,535,186 was issued on August 13, 1985, and assigned to Wyeth. It teaches that venlafaxine is "useful in the treatment of depression, for which purpose they may be administered orally or parenterally in an amount sufficient to alleviate the symptoms of depression."[101] Venlafaxine may be "compounded into any of the usual oral dosage forms including tablets [and] capsules[.]"[102] The '186 patent is prior art under 35 U.S.C. § 102(a), since it describes an invention patented in the United States before the invention of the patents-in-suit.

Alza's international PCT application number WO 94/27589, filed on May 27, 1994, describes an extended-release formulation of venlafaxine. It is directed toward providing a "once-a-day controlled-release dosage form to deliver [venlafaxine] orally to a patient in need of therapy."[103] It teaches that one can "deliver the therapeutic drug in a therapeutically effective amount at a controlled rate over an extended period of time to the patient in need of said

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[97] Ex. 16 ('475 patent) at 2:10-16 ("For example, the spheroids may be manufactured on a conventional spheroniser in which a horizontal, rough-surfaced plate rotates inside a stationary vertical cylinder, and then film coated in conventional manner in a perforated coating drum, and finally the film coated spheroids filled into hard gelatine capsules using a conventional encapsulation machine.")

[98] *Id.* at 2:20-23 ("Propranolol hydrochloride (60kg.) and microcrystalline cellulose (Avicel-PH-101; 40kg.) were blended together in a 450 litre planetary mixer.")

[99] *Id.* at 1:33-36 ("the said spheroids having a film coat comprising ethylcellulose optionally together with hydroxypropyl methylcellulose").

[100] *Id.* at 2:15-16 ("finally the film coated spheroids filled into hard gelatine capsules using a conventional encapsulation machine.")

[101] Ex. 1 at 10:17-20.

[102] Ex. 1 at 10:34-35.

[103] Ex. 22 (Alza PCT Application) at 6:10-12.

therapy."[104] The '589 application is prior art under at least 35 U.S.C. § 102(b), since the application was published on December 8, 1994, more than one year before the March 25, 1996 effective filing date of the patents-in-suit.[105]

United States Patent No. 5,506,270 was filed on January 30, 1995 and issued on April 9, 1996, and assigned to Wyeth. It describes a method of providing therapy by administering venlafaxine "in . . . sustained oral administration form or time-release form, which may be used to spread the dosage over time, such as for once-a-day applications."[106] The '270 patent is prior art under 35 U.S.C. § 102(e)(2), since it was filed on January 30, 1995, before the invention of the patents-in-suit, making it a "patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent."

G. The level of ordinary skill in the art.

There is no significant dispute about the level of ordinary skill in the art. According to Wyeth's expert, Dr. Sawchuk:

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III. STANDARD OF REVIEW[108]

Rule 56(c) of the Federal Rules of Civil Procedure provides that a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions,

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[104] *Id.* at 27.

[105] *Id.* (cover page).

[106] Ex. 37 ('270 patent) at 5:25-27.

[107] Ex. 39 (excerpt from the expert report of Dr. Ronald Sawchuk) at 10-11.

[108] *Lacy v. AMTRAC*, 507 F. Supp. 2d 438 (D. Del. 2007); *Harrison v. Christopher*, 489 F.

answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a triable dispute of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party.[109]

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts . . . . In the language of the Rule, the non-moving party must come forward with specific facts showing that there is a genuine issue for trial."[110] But the mere existence of some evidence in support of the nonmovant will not be sufficient to support denial of summary judgment; there must be enough evidence to enable a jury to reasonably find for the nonmovant on that issue.[111] Thus, if the evidence is "merely colorable, or is not significantly probative," summary judgment is appropriate.[112]

IV. ARGUMENT

A. Under Impax's claim construction, Impax's product does not infringe the patents-in-suit.

1. Impax's product does not literally infringe the patents-in-suit.

All of the asserted claims, properly construed, require "a formulation comprising venlafaxine hydrochloride, MCC and, optionally, HPMC[.]"[113] Impax's product contains no MCC.[114] For this reason, it cannot literally infringe the asserted claims.

Supp. 2d 375 (D. Del. 2007).

[109] *Valhal Corp. v. Sullivan Assocs., Inc.*, 44 F.3d 195, 200 (3d Cir. 1995).

[110] *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (internal quotations and citations omitted).

[111] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

[112] *Id.*

[113] *See* Ex. 40 (Impax's April 13, 2007 Proposed Claim Constructions).

[114] Ex. 38 (excerpt from Impax ANDA listing ingredients in Impax's product) IMPAX0003789-791.

2. Impax's product does not infringe the patents-in-suit under the doctrine of equivalents.

The purpose of the doctrine of equivalents is to ensure that a patentee's claims can cover unanticipated embodiments of the invention that are only insubstantially different from what is expressly claimed in the patent itself.[115] But the doctrine is limited in at least two important ways. First, a patentee cannot seek to recapture claim scope that it disclosed in the specification but failed to claim expressly. Second, a patentee cannot recapture claim scope that it surrendered while prosecuting the patent applications. Wyeth's efforts to assert infringement here under the doctrine of equivalents are precluded by both rules.

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a. Wyeth disclosed but did not claim and so may not argue that it is an infringing equivalent.

When a patentee describes subject matter in the specification but does not claim that subject matter, the patentee may not use the doctrine of equivalents to "recapture subject matter deliberately left unclaimed."[116] Instead, that unclaimed subject matter is dedicated to the public. A teaching is dedicated to the public "if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description."[117]

Here, Wyeth's patents disclosed, but did not claim,

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Accordingly, because Wyeth disclosed but did not expressly claim

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[115] *Johnson & Johnston Assocs. v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc).

[116] *Id.* at 1059-60.

[117] *PSC Computer Prods. Inc. v. Foxconn Int'l.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

[118] REDACTED

[119] REDACTED

REDACTED in an extended release formulation of venlafaxine, it dedicated REDACTED the public, and thus is barred from attempting to recapture REDACTED through the doctrine of equivalents.

b. Wyeth's conduct during the prosecution history of the patents-in-suit estops it arguing that Impax's formulation is equivalent.

When "the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent."[120] Where the patentee acquiesces in the examiner's limitation of the scope of the claims in order to avoid prior art, the patentee's "decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim," and the surrendered claim scope may not be recaptured by recourse to the doctrine of equivalents.[121]

In a parent application to the patents-in-suit, Wyeth initially proposed apparatus claims that were explicitly limited to formulations of venlafaxine, MCC and, optionally, HPMC, and method claims that did not explicitly recite those ingredients.[122] The examiner found those method claims invalid over a patent that disclosed an extended release formulation of venlafaxine, U.S. Patent No. 5,506,270. Wyeth and the examiner then participated in a discussion, during which Wyeth agreed that the method claims would be narrowed to a method of administering the specific claimed formulations. The examiner entered such an amendment, and gave Wyeth an opportunity to file an amendment if it did not agree with the examiner's action. Wyeth filed no such amendment.[123]

In acquiescing to the examiner's amendment, Wyeth conceded "that the invention as

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[120] *Festo Corp. v. Shokestsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-34 (2002).

[121] *Id.* at 734.

[122] Ex. 35 (U.S. Patent Application No. 08/821,137, as filed at 12) at WYETH 002-000805.

[123] *Id.* at WYETH 002-000850 (Examiner Hulina's July 30, 1997 Interview Summary in connection with the '137 Application).

patented does not reach as far as the original claim"[124]—that is, that the invention as patented does not reach formulations that do not include MCC as an ingredient, under the doctrine of equivalents or otherwise. It does not matter that Wyeth acquiesced to the examiner's rejection in a *parent* application. "The prosecution history must be examined as a whole in determining whether estoppel applies."[125] In *Mark I Marketing Corp. v. R.R. Donnelley & Sons Co.*,[126] the patentee, Mark I, first filed an application which "broadly claimed a process for reproducing color images by printing with two printing plates and two inks."[127] When that application was rejected over prior art, "[i]nstead of responding to the rejection, Mark I filed [a] continuation-in-part application with new claims."[128] The CIP application claims, too, were rejected over prior art, and "[r]ather than respond to the rejection, Mark I again chose to file a continuation-in-part application with new claims."[129] That last application matured into the patent-in-suit.[130] The Federal Circuit held that prosecution history estoppel applied to limit the application of the doctrine of equivalents to the patent-in-suit based on the patentee's conduct in the parent applications. "The fact that the claims of the [ultimately issued] application were not themselves rejected by the Patent Office or amended by Mark I does not call for a different result," the Federal Circuit held, because "the prosecution must be viewed as a whole to determine whether and what subject matter was surrendered to procure issuance of the patent."[131] Here, as in *Mark I*, Wyeth acquiesced in an examiner's rejection. Like Mark I, Wyeth is estopped from recapturing that claim scope under the doctrine of equivalents.

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[124] *Festo*, 535 U.S. at 734

[125] *Wang Lab., Inc. v. Toshiba Corp.*, 993 F.2d 858, 867 (Fed. Cir. 1993).

[126] 66 F.3d 285 (Fed. Cir. 1995)

[127] *Id.* at 291.

[128] *Id.*

[129] *Id.*

[130] *Id* at 291-92.

[131] *Id.* at 292.

B. Under Wyeth's claim construction, the asserted claims are invalid for lack of written description and enablement.

If this Court accepts Wyeth's construction of the term "extended release formulation," the asserted claims are invalid for failure to comply with 35 U.S.C. § 112(1). That section requires:

> The specification shall contain a **written description of the invention**, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to **enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same**, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(emphasis added). The patents-in-suit are invalid for failure to satisfy two of this section's requirements: the "written description" requirement and the "enablement" requirement. Each is discussed in turn.

1. The patents-in-suit do not satisfy the written description requirement.

Wyeth's asserted claims fail to meet the statutory written description requirement of Section 112(1). To fulfill the written description requirement, a patent specification must demonstrate that the inventors were in possession of "*the invention*, with all its claimed limitations."[132] Accordingly, "a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope."[133] Because the contents of the specification are not disputed facts, on summary judgment, "a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification."[134]

Under Wyeth's proposed construction, the claim term "extended release formulation" covers any "formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing

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[132] *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis in original)).

[133] *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002).

[134] *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004) (upholding a grant of summary judgment of invalidity for inadequate written description).

frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." Yet the specification only describes one extended-release formulation comprising venlafaxine, MCC, and optional HPMC. Because the specification repeatedly describes that formulation as the "invention" of the patent, if the Court construes the claims to cover *any* extended release formulation, then it must also deem those claims invalid for lack of written description.

The specification describes the formulation on venlafaxine, MCC and HPMC as *the invention*: "The formulations *of this invention* comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose."[135] Similarly, the patent specification explains that "The extended release formulations *of this invention* are comprised of 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose."[136] This formulation is not described as a preferred embodiment; instead, the patentees describe narrower preferred embodiments of this invention, all of which are specific examples of "the invention" comprising venlafaxine, MCC and optionally HPMC. Every example in the specification conforms to this definition of the "invention"; each example comprises venlafaxine hydrochloride, MCC and, optionally, HPMC.[137]

This focus on the specific ingredients in the extended release formulation makes sense in light of the specification's description of the problem that the inventors set out to solve. Specifically, the specification asserts that it was completely unexpected that an extended release

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[135] Ex. 11 ('171 Patent) at 2:63-3:2 (emphasis added).

[136] *Id.* at 4:9-12 (emphasis added).

[137] *Id.* at 5:33-10:57.

formulation could be made because venlafaxine is a highly water soluble drug.[138] Thus the patent lays out the difficulties that the inventors encountered in finding a workable formulation, including their failure to make an extended release formulation using hydrogel tablet technology and their failure to achieve a workable formulation REDACTED The specification thus makes clear that the invention was the specific formulation that solved the posited problem.

Having described but one invention in the specification, the claims cannot properly cover extended-release formulations other than those comprising venlafaxine hydrochloride, MCC and, optionally, HPMC. As *Cooper Cameron* explains, "a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope."[139]

This case is similar to *LizardTech, Inc. v. Earth Resource Mapping, Inc.*[140] *LizardTech* dealt with technology known as "wavelet transforms," which allow digital images to be compressed with little loss of information.[141] The patent claims were interpreted to cover a seamless discrete wavelet transform (DWT). The district court construed the claims broadly to cover any method of creating the seamless DWT, but the specification disclosed only one method for creating a seamless DWT. The Federal Circuit characterized the issue as follows:

> The trouble with allowing claim 21 to cover all ways of performing DWT-based compression processes that lead to a seamless DWT is that there is no support for such a broad claim in the specification. The specification provides only a single way of creating a seamless DWT, which is by maintaining updated sums of DWT coefficients. There is no evidence that the specification contemplates a more generic way of creating a seamless array of DWT coefficients.[142]

Accordingly, the court found the broader claims invalid for lack of written description. The Federal Circuit concluded:

> a patentee cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the

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[138] *Id.* at 4:57-60.

[139] 291 F.3d at 1323.

[140] 424 F.3d 1336 (Fed. Cir. 2005).

[141] *Id.* at 1337.

[142] *Id* at 1334.

> thing claimed. For that reason, we hold that the description of one method for creating a seamless DWT does not entitle the inventor of the '835 patent to claim any and all means for achieving that objective.[143]

The situation here is almost identical to *LizardTech*. The specification underlying the asserted claims discloses only one extended-release venlafaxine formulation. If the Court agrees with Wyeth's proposed claim construction, and construes the claims broadly to cover almost any extended-release venlafaxine formulation, then those claims lack adequate written description. The description of one method for formulating extended-release venlafaxine does not entitle Wyeth to claim any and all formulations for achieving extended release of venlafaxine.[144]

To the extent Wyeth argues that the patent more broadly relates to treatment methods, the specification still only refers to the use of formulations containing venlafaxine, MCC, and optional HPMC. The specification teaches that "[t]hrough administration of the venlafaxine *formulation of this invention*, there is provided a method for obtaining a flattened drug plasma concentration to time profile[.]"[145] "The *formulations of this invention* comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, MCC and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC."[146] Thus, if the Court accepts Wyeth's claim construction, it must also hold the asserted claims invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112(1).

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[143] *Id.* at 1346.

[144] *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (where the specification described only a cup with a conical shape, claims which were generic as to the shape of the cup were not supported by written description). *See also Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (finding a lack of written description because "a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA"); *Gentry Gallery*, 134 F.3d at 1479 (where the patent discloses only a recliner with controls on its console, "the patent's disclosure does not support claims in which the location of the recliner controls is other than on the console"); *Chiron v. Genentech*, 363 F.3d 1247, 1258-59 (Fed. Cir. 2004).

[145] Ex. 11 ('171 patent) at 2:20-24.

[146] *Id.* at 2:63-3:2.

2. The patents-in-suit do not satisfy the enablement requirement.

The "enablement" requirement mandates that "as part of the *quid pro quo* of the patent bargain, the applicant's specification must enable one of skill in the art to practice the full scope of the claimed invention."[147] While "a specification need not disclose what is well known in the art,"[148] there "must be a reasonable enablement of the scope" of the claimed subject matter.[149] In particular, where the specification "expressly teaches against" a particular embodiment, the specification is deemed not to have enabled that embodiment.[150]

The Federal Circuit's decision in *AK Steel* illustrates this rule. In that case, the patent in suit claimed a steel strip coated with an aluminum coating that "contains up to about 10% by weight silicon."[151] In the specification, however, the patentee AK Steel stated that its attempts to coat a steel strip with an aluminum coating containing about 10% silicon had failed, and that in order to make coating practical, the "silicon contents in the coating metal should not exceed about **0.5%** by weight."[152] AK Steel sued Sollac, whose aluminum coating contained about 8.5% silicon.[153] Sollac argued that because the specification stated that using a coating containing more than 0.5% silicon wouldn't work, the specification had not enabled subject matter encompassing Sollac's coating.[154] The Federal Circuit agreed. It stated that the specification could not have enabled subject matter encompassing Sollac's coating "because it expressly teaches against it."[155] "Worse than being silent as to that aspect of the invention, the specification clearly and strongly warns that such an embodiment [as Sollac's] would not

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147 *AK Steel Corp v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

148 *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

149 *AK Steel*, 344 F.3d at 1244.

150 *Id.*

151 *AK Steel* at 1237.

152 *Id* at 1236.

153 *Id.* at 1238.

154 *Id.* at 1243.

155 *Id.* at 1244.

[work]."[156] Because AK Steel's "statement discourages experimentation with coatings having more than 0.5% silicon, undue or otherwise," the court held, it the specification was "inadequate as a matter of law."[157] "It tells the public that higher amounts of silicon will not work. Nothing further need be said about the matter."[158]

Likewise, here, Wyeth's statement about REDACTED in the specification tells the public that REDACTED

—will not work. REDACTED

Far from enabling REDACTED the specification "expressly teaches against" them.[161] As in *AK Steel*, because the specification "discourages experimentation" with REDACTED it is "inadequate as a matter of law" as an enablement of such formulations.[162]

C. In the alternative, the patents-in-suit are invalid for failure to name one of the joint inventors, REDACTED

Section 102(f) of the Patent Act "makes the naming of the correct inventor or inventors a condition of patentability; failure to name them renders a patent invalid."[163] "All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or

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156 *Id.*

157 *Id.*

158 *Id.*

159 Ex. 11 ('171 Patent) at 5:4-6.

160 *Id.* at 6:6.

161 *AK Steel*, 344 F.3d at 1244.

162 *Id.*

163 *Pannu v. Iolab,* 155 F.3d 1344, 1349-50 (Fed. Cir. 1998).

the current state of the art."[164]

Here, if Wyeth is correct that there is any patentable invention, the patents-in-suit are invalid because they fail to name a joint inventor, REDACTED is an expert in the development, selection, and use of pharmaceutical excipients—the ingredients that go into dosage forms that are not pharmaceutically active. In formulating Effexor XR, as recounted above in section II.A.6, REDACTED While extruding the granulation mix, "heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids."[165]

REDACTED

Almost immediately, Sherman had success in making spheroids. As the patents recount, "[a]ddition of HPMC 2208 to the venlafaxine hydrochloride-MCC mix made production of spheroids practical."[166]

REDACTED contribution easily meets the standard set forth in *Pannu*. That contribution rendered reduction to practice possible and thus was clearly "significant." Even under Wyeth's expansive view of the scope of the "full invention,"[167] REDACTED contribution was significant: he

REDACTED

Finally, either did more than "merely explain to the real inventors well-known concepts and/or the current state of the art,"[168] or there is no invention here at all. Assuming that any part of the invention was novel and non-obvious, it was the specific formulation claimed—

REDACTED

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[164] *Id.* at 1351.

[165] Ex. 11 ('171 Patent) at 5:8-11.

[166] *Id.* at 5:1-13.

[167] *Pannu* at 1351.

[168] *Id.* at 1351.

The magnitude of REDACTED contribution is clear when it is compared with the contribution of John Lamer, a Wyeth employee who was named as an inventor. Lamer's sole contribution was REDACTED

If Lamer was a joint inventor for REDACTED was certainly an inventor for REDACTED

Because REDACTED made the contribution that "made production of spheroids practical," he was a joint inventor. Because he was not named on the face of the patents-in-suit, they are invalid.

D. If the preambles limit claim scope, the claims referring to "therapeutic metabolism" are invalid as indefinite.

Several of the asserted claims refer to the "therapeutic metabolism of plural daily doses" of venlafaxine.[170] This term has no meaning to a person of skill in the art, and renders invalid the claims in which it appears in the preambles are claim limitations.

Every patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[171] Claims that are "not amenable to construction" or "insolubly ambiguous" are indefinite.[172] "[I]f reasonable efforts at claim construction prove futile," a claim term should be deemed indefinite.[173] Claims are *required* to be "sufficiently precise" so that a potential competitor may "determine whether or not he is infringing . . . ."[174] Where a claim fails this test, it is "invalid for failure to satisfy the 'definiteness' requirement of section 112, second paragraph."[175]

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[169] Ex. 46 (Deposition of John Lamer in re *Wyeth v. Teva Pharmaceuticals USA, Inc.*) at 270:13-21, 275:19-276:5.

[170] Namely, claims 21, 24, and 25 of the '171 patent and claims 2, 5, and 6 of the '925 patent.

[171] 35 U.S.C. § 112.

[172] *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005).

[173] *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

[174] *Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

[175] *Id.*

The term "therapeutic metabolism of plural daily doses" simply has no meaning to a person of skill in the art.[176] While "therapeutic" and "metabolism" each have meanings, the combination of the two words is not commonly used by persons of skill in the art, and thus has no ordinary meaning.[177] Nor does the context of the claim or specification clarify what is meant by "therapeutic metabolism of plural daily doses." Indeed, the specification of the patents cannot provide an answer for a very simple reason: the specification does not even use the term "therapeutic metabolism."

Because it lacks any discernible meaning, the phrase "therapeutic metabolism of plural daily doses" does not allow a competitor such as Impax to determine whether or not it is infringing, and thus renders the claims in which it appears invalid as indefinite.

[176] Ex. 47 (Rebuttal Expert Report of Arthur H. Kibbe, Ph.D.) ¶ 81.

[177] *Id.*

V. CONCLUSION

For all the foregoing reasons, the Court should rule that Impax does not infringe Wyeth's patents in suit and that Wyeth's patents are invalid, and grant summary judgment in favor of Impax.

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